

1.10 Configure Sponsor Level AE Notification Triggers

Description

This use case will capture configuration of AE notification triggers at the sponsor level. A sponsor (e.g SWOG) will dictate the triggers for notification on its protocols. The triggers are invoked when an AE is created and stopped when all notifications are completed or the notification time period has passed (*SIG: verify if this is valid).

Actors

The System Administrator (SA), PI or any other designated user of *AERS*sm with appropriate role authority.

Pre-Conditions

The actor has identified and assigned all personnel to appropriate roles and configured email addresses or email lists for notification. The actor has successfully logged into the system.

Basic Course

1.The actor selects classification option to configure Sponsor Level Notification Triggers.

2.*AERS*sm presents a Trigger Builder. The actor configures the following AE notification trigger rules or turns them 'OFF' if not applicable.

- TRIGGER CATEGORY: selects from pre-filled list or input if not found
- TRIGGER TITLE: inputs trigger title in text field
- AE CATEGORY: selects AE category from pre-filled list if interested in creating a trigger for a specific AE
- AE TERM: selects AE Term from pre-filled list if interested in creating a trigger for a specific AE
- PROTOCOL ID: selects 'OFF' or 'ALL' or one or more protocols from key word search or ID
- SPONSOR ID: selects 'OFF' or a sponsor from key word search or ID
- GRADE: Selects equality symbol and inputs targeted grade
 - >=, >, <, <=
 - 1,2,3,4 or 5
- HOSPITALIZATION: selects:
 - Hospitalized
 - Extended Hospitalization
 - No
- HOSPITALIZATION HRS: inputs hours of hospitalization
- EXPECTEDNESS: selects 'OFF' or one below
 - Expected
 - Unexpected
- ATTRIBUTION: selects 'OFF' or one or more below
 - Unrelated
 - Unlikely Related
 - Possibly Related
 - Probably Related
 - Definitely Related

- PHASE: selects 'OFF' or one or more below
 - Pilot/Feasibility,
 - Phase I
 - Phase II
 - Phase III
 - Phase IV
- REPORT PERIOD: enter number of business days for total reporting period

3. The actor configures messages, timing and escalation rules for notification (Use Case 1.12).

4. The actor submits selection and confirms notification rule summary.

Post Conditions

The actor has created one or more sponsor level AE notification triggers.

Alternate Course

Pending

Use Case Dependency

1.5 Create AE

1.6 AE Data Collection

1.8 Configure Protocol Staff for AE Notification

4.2 Create Report

Data Item

Data Item	Type	Validation
Trigger Category	Required	Pending
Trigger Title	Required	Pending
AE Category	Not Required	Pending
AE Term	Not Required	Pending
Protocol ID	Not Required	Pending
Sponsor ID	Not Required	Pending
Grade	Required	Pending
Hospitalization	Not Required	Pending
Hospitalization Hrs	Not Required	Pending
Expectedness	Not Required	Pending
Attribution	Not Required	Pending
Phase	Not Required	Pending
Notification Period	Required	Pending
Protocol Staff Roles	Required	Pending

Notes

None identified at this time.

Risks

Pending

Use Case dependency

13.0 User login

1.1 Create Protocol Data for AE Abstraction

1.2 Create and Link Study Participant to Protocol

1.5 Create AE Entry

4.2 Create Report

1.11 Configure Protocol Level AE Notification Triggers

Description

This use case will capture configuration of AE notification triggers at the protocol level. A protocol will dictate the triggers for notification based on its requirements. The triggers are invoked when an AE is created and stopped when all notifications are completed or the notification time period has passed (*SIG: verify if this is valid).

Actors

The System Administrator (SA), PI or any other designated user of *AERS*sm with appropriate role authority.

Pre-Conditions

The actor has identified and assigned all personnel to appropriate roles and configured email addresses or email lists for notification. The actor has successfully logged into the system.

Basic Course

1. The actor selects the classification option to configure Protocol Level Notification Triggers.
2. **The actors selects option for this protocol trigger to take priority over other triggers (Discussion item).**
3. *AERS*sm presents a Trigger Builder. The actor configures the following AE notification trigger rules or turns them 'OFF' if not applicable.
 - TRIGGER CATEGORY: selects from pre-filled list or input if not found
 - TRIGGER TITLE: inputs trigger title in text field
 - AE Category: selects AE category from pre-filled list if interested in creating a trigger for a specific AE
 - AE Term: selects AE Term from pre-filled list if interested in creating a trigger for a specific AE
 - PROTOCOL ID: selects 'OFF' or 'ALL' or one or more protocols from key word search or ID
 - SPONSOR ID: selects 'OFF' or a sponsor from key word search or ID
 - GRADE: Selects equality symbol and inputs targeted grade
 - >=, >, <, <=
 - 1,2,3,4 or 5

- HOSPITALIZATION: selects:
 - Hospitalized
 - Extended Hospitalization
 - No
- HOSPITALIZATION HRS: inputs hospitalization hours
- EXPECTEDNESS: selects 'OFF' or one below
 - Expected
 - Unexpected
- ATTRIBUTION: selects 'OFF' or one or more below
 - Unrelated
 - Unlikely Related
 - Possibly Related
 - Probably Related
 - Definitely Related
- PHASE: selects 'OFF' or one or more below
 - Pilot/Feasibility,
 - Phase I
 - Phase II
 - Phase III
 - Phase IV
- REPORT PERIOD: enter number of business days for total reporting period

4. The actor configures the notification, timing and escalation rules via a notification manager (UseCase 1.12).

5. The actor submits selection and confirms notification rule summary.

Post Conditions

The actor has created one or more protocol level notification triggers.

Alternate Course

Pending

Use Case Dependency

1.5 Create AE

1.6 AE Data Collection

1.8 Configure Protocol Staff for AE Notification

4.2 Create Report

Data Item

Data Item	Type	Validation
Trigger Category	Required	Pending
Trigger Title	Required	Pending
AE Category	Not Required	Pending
AE Term	Not Required	Pending
Protocol ID	Not Required	Pending
Sponsor ID	Not Required	Pending
Grade	Required	Pending
Hospitalization	Not Required	Pending
Hospitalization Hrs	Not Required	Pending
Expectedness	Not Required	Pending
Attribution	Not Required	Pending
Phase	Not Required	Pending
Notification Period	Required	Pending
Protocol Staff Roles	Required	Pending

Notes

None identified at this time.

Risks

Pending

Use Case dependency

13.0 User login

1.1 Create Protocol Data for AE Abstraction

1.2 Create and Link Study Participant to Protocol

1.5 Create AE Entry

4.2 Create Report

1.12 Configure Messages, Timing and Escalation Rules for Notifications

Description

This use case will describe configuration of a Notification Manager, a rules based component that will broker and consolidate notifications from the institution, sponsor and protocol triggers

Actors

The System Administrator (SA), PI or any other designated user of *AERS*sm with appropriate role authority.

Pre-Conditions

All personnel have been assigned to appropriate roles. Email addresses or email lists for notifications exist. The actor has successfully logged into the system and has created a trigger for which notification rules need to be defined.

Basic Course

1. The actor selects the Notification Manager option from the Trigger Builder.
2. The actor configures reporting days for protocol staff notification
 - Select the day/hrs of reporting period (e.g. If 10 day reporting period, select day 1 if notification should occur on this day)
 - Select one or more protocol staff roles.
 - Select notification method (e.g. email, pager, application notification on login)
 - Complete notification message (e.g. Subject: "IRB Reportable AE", Text: "AE created on *date and met IRB SAE reporting requirements. AE data needs completion for report generation")
 - Repeat for all interested days of reporting period, especially day just prior to reporting deadline and, optionally, x days after reporting deadline (e.g. to enter follow-up data)
3. The actor checks "APPLICATION NOTIFICATION ON LOGIN", if application should post notifications to staff members on login.
4. **Course for consolidation of notifications pending discussion of issues.**

Post Conditions

The actor has created messages, timing and escalation rules for notifications related to institution, sponsor and protocol AE triggers.

Alternate Course

Pending

Use Case Dependency

- 1.5 Create AE
- 1.6 AE Data Collection
- 1.8 Configure Protocol Staff for AE Notification
- 4.2 Create Report

Data Item

Pending review of sample NotificationTiming and Escalation Rules (RP 19)

Data Item	Type	Validation

Notes

None identified at this time.

Risks

Pending

Use Case dependency

- 13.0 User login
- 1.1 Create Protocol Data for AE Abstraction
- 1.2 Create and Link Study Participant to Protocol
- 1.5 Create AE Entry
- 4.2 Create Report